

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY ) MDL No. 1456  
AVERAGE WHOLESALE PRICE LITIGATION ) Master File No. 01-12257-PBS  
 ) Subcategory Case No. 06-11337  
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 ) Judge Patti B. Saris  
THIS DOCUMENT RELATES TO: )  
*State of California, ex rel. Ven-A-Care of the Florida* ) Magistrate Judge  
*Keys, Inc. v. Abbott Laboratories, Inc., et al.* ) Marianne B. Bowler  
Case No: 1:03-cv-11226-PBS )  
 )

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**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF  
MOTION FOR PARTIAL SUMMARY JUDGMENT**

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## I. INTRODUCTION

In this action, the State of California and Ven-A-Care (“Plaintiffs”) allege that Dey, L.P. and Dey, Inc. (“Dey”), Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (“Mylan”), and Sandoz Inc. (“Sandoz”) (collectively, “Defendants”)<sup>1</sup> systematically defrauded California’s Medicaid program (“Medi-Cal”). They did so by reporting grossly inflated Average Wholesale Prices (“AWPs”) for certain of their drugs to First DataBank (“FDB”), the compendium price publisher used by Medi-Cal in determining reimbursement for providers<sup>2</sup> that dispensed Defendants’ products to Medi-Cal beneficiaries. By submitting inflated AWPs to FDB, which were often more than 10 times the actual average prices paid by providers for those products, Defendants knowingly caused Medi-Cal to pay far more for their drugs than it should have paid under the governing reimbursement statutes and regulations. The relevant time period alleged in California’s First Amended Complaint (“FAC”) is January 1, 1994 through December 31, 2004.

That the Defendants’ reported drug prices were inflated is beyond question. This Court has previously found as much:

The drug prices alleged by [California] cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs that they are by their very nature fraudulent.

*In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 174 (D. Mass. 2007) (hereinafter, “*California*”).

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<sup>1</sup> Dey, Mylan and Sandoz are, effectively, the only remaining defendants in the captioned California case. A fourth defendant group, Schering Plough Inc. and Warrick Pharmaceutical Corp., has reached a settlement in principle with California under the auspices of mediator Professor Eric Green. California reached similarly mediated settlements with all other defendants subsequent to the Courts’ order of March 22, 2007, denying Defendants’ Joint Motion to Dismiss.

<sup>2</sup> As used herein, “providers” does not refer to physicians, but is limited to retail and “closed door” pharmacies (i.e., pharmacies that provide drugs to long-term care facilities). No physician administered drugs are at issue.

Pursuant to Fed. R. Civ. P. 56 and this Court's Local Rule 56.1, Plaintiffs now move for partial summary judgment against all Defendants as to liability on the First and Second Causes of Action in the FAC, which state claims for relief under the California False Claims Act ("CA FCA"), CAL. GOV'T CODE § 12651.<sup>3</sup>

Medi-Cal is the main source of health insurance for about 6.8 million Californians, and accounted for 19% of California's General Fund spending in fiscal year 2008-2009.<sup>4</sup> Medi-Cal is the largest Medicaid program in terms of people served, the second largest in terms of dollars spent (\$47 billion annually), and the primary (if not exclusive) source of health coverage for one in ten Californians under 65, one in three of the State's children, and the majority of Californians living with AIDS.<sup>5</sup> In 2002 alone, the last year that the California Health Care Foundation conducted a Medi-Cal pharmacy benefit study, Medi-Cal expended \$2.5 billion just in fee-for-service pharmacy benefits. In 2001, approximately the halfway point of the relevant time period of California's action, an average of 933,338 fee-for-service Medi-Cal beneficiaries used their pharmacy benefit every month, at an annual cost of \$3,150 per participating beneficiary.<sup>6</sup>

The governing statutes and regulations make clear that Medi-Cal used AWP as its primary reimbursement benchmark for the fee-for-service drugs that are the subject of this litigation (the "Subject Drugs");<sup>7</sup> that AWP was used by the State as a means to estimate

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<sup>3</sup> See FAC filed August 25, 2005, docket 1679, at 55-58.

<sup>4</sup> California Healthcare Foundation, *California Healthcare Almanac: Medi-Cal Facts and Figures*, p. 2, (September 2009), in pdf format at <http://www.chcf.org/documents/policy/MediCalFactsAndFigures2009.pdf> (or <http://tiny.cc/Qe3tl>).

<sup>5</sup> *Id.*, at p. 4.

<sup>6</sup> California Health Care Foundation, *The Medi-Cal Pharmacy Benefit (Fact Sheet No. 12)*, <http://www.chcf.org/topics/medi-cal/index.cfm?itemID=20426&subtopic=CL367&subsection=medical101> (or <http://tiny.cc/NKLEX>).

<sup>7</sup> The Subject Drugs are comprised of 394 National Drug Code (NDC) designations, including 217 Mylan NDCs, 149 Sandoz NDCs, and 28 Dey NDCs.

providers' acquisition costs; and that the term AWP was used in accord with its plain meaning to mean the average price at which wholesalers sold drugs to Medi-Cal providers. Hence, as this Court has held in other contexts (as discussed below), the term "Average Wholesale Price," as used in the relevant California statute and regulation, should be given its plain meaning. Once that interpretation is applied, it is clear that there are no genuine issues of material fact as to any elements necessary to show liability on the part of Defendants.

Plaintiffs' claims under the CA FCA are simple and straightforward, and there are no factual disputes precluding summary adjudication as to liability. It is undisputed that (1) the Defendants reported AWPs for their Subject Drugs to FDB; (2) FDB published Defendants' reported AWPs; (3) Medi-Cal relied on the AWPs to determine provider reimbursement for the Subject Drugs; (4) the AWPs for the Subject Drugs were false in that they materially exceeded any reasonable estimate of the Subject Drugs' actual average wholesale prices; (5) Defendants' false AWPs caused the submission of false claims by Medi-Cal providers; and (6) the Defendants acted knowingly as defined in the CA FCA.

The particular facts germane to each Defendant differ in some respects, and Plaintiffs have filed separate Local Rule 56.1 Statements of Undisputed Material Facts as to each. On a general level, however, the core facts are similar.

Notwithstanding the statutory mandate that AWPs were to be used by Medi-Cal as a price reference for determining estimated acquisition cost for the Subject Drugs, Defendants did not report prices that approximated providers' acquisition costs for the Subject Drugs. Each instead reported AWPs that were either pegged to a brand's or competitor's AWP, or that otherwise met the "needs" of their customers by ensuring large spreads between what the providers paid to acquire the drugs, and what providers received in AWP-based reimbursement by Medi-Cal.

Each Defendant knowingly failed to adjust its AWPs to reflect the declining prices that characterized the market for their generic drugs, and some occasionally raised AWPs to increase their sales. The spreads on the Subject Drugs were large, sometimes in excess of 800% for Dey, and 2000% for Mylan and Sandoz. In over 93% of the relevant periods for Dey, and over 95% for Mylan and Sandoz, the spreads on the Subject Drugs exceeded 100%.

Moreover, Defendants' "government knowledge" defense is neither factually nor legally supportable. There is nothing in the record to show that Defendants informed Medi-Cal of the actual prices generally and currently paid by providers for the Subject Drugs, much less that Medi-Cal was apprised of, and approved, Defendants' practice of reporting the type of grossly inflated AWPs at issue herein. Further, it is well settled that when Defendants chose to participate in Medi-Cal, they undertook the duty to familiarize themselves with the legal requirements of the program. *See, e.g., Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984); *North Mem'l Med. Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995). These include the procedures and legal requirements applicable to reimbursements. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001). Each of the Defendants chose to have Medi-Cal reimburse for its drugs, and, as a matter of law, each is consequently charged with the knowledge of the relevant statutes and regulations. Defendants were therefore required to know that California's definition of Estimated Acquisition Cost ("EAC"), of which AWP was a reference component, "means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." CAL. WELF. & INST. CODE § 14105.45(a)(4) (West 2009). Because their own records indisputably establish that the AWPs they reported to FDB bore no reasonable

relation to prices that were generally and currently being paid by providers, there is no genuine issue as to Defendants' scienter. Defendants are therefore liable under the CA FCA.

## II. MEDI-CAL PHARMACEUTICAL REIMBURSEMENT METHODOLOGY

Federal law requires that Medicaid programs reimburse providers for drugs dispensed to eligible participants at prices no greater than the estimated price the providers paid for these drugs, plus a dispensing fee. As this Court summarized in *Massachusetts v. Mylan Labs., Inc.*, 608 F. Supp. 2d 127 (D. Mass. 2008) (hereinafter, "Massachusetts"):

Under federal Medicaid regulations, a state Medicaid program's payments for a drug may not exceed the "estimated acquisition cost" of the drug plus a reasonable dispensing fee, where the "estimated acquisition cost" ("EAC") is defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers."

*Massachusetts*, 608 F. Supp. 2d at 132 (quoting 42 C.F.R. § 447.301 (2006) at 132). In addition, federal regulations generally require that payments for multi-source drugs for which there are Federal Upper Limits ("FULs") not exceed, in the aggregate, the ceiling set by such FULs. *Id.*, citing 42 C.F.R. § 447.331 (2007). "The Medicaid Act further requires that a Medicaid Plan's payment rates and any changes to those rates be set by a 'public process,'" which gives interested parties the opportunity to comment and requires the Agency to articulate the justification for the rates it adopts. *Massachusetts*, 608 F. Supp. 2d at 132.

The federal regulations have been implemented by the relevant California statutes and regulations, which collectively provide that Medi-Cal reimburses providers for drugs at the estimated acquisition cost of the drug, plus a dispensing fee. CAL. WELF. & INST. CODE § 14105.45(b)(1) (West 2009). Throughout the relevant time period, the reimbursement amount for the Subject Drugs was the lowest of the provider's Usual and Customary cost, or (a) the product's Estimated Acquisition Cost ("EAC"); (b) the state's Maximum Allowable Ingredient

Cost (“MAIC”) for the product;<sup>8</sup> or (c) the FUL. California’s EAC has always been set at AWP less a certain percentage discount (i.e., less 5% from before January 1, 1994 through November 2002; less 10% from December 2002 through August 2004; and less 17% from September 2004 through the present. (Gorospe Decl., at ¶ 5b, attached as Ex. 1 to the Declaration of Nicholas N. Paul in Support of Motion for Partial Summary Judgment as to Defendant Dey (“Paul Dey Decl.”), Declaration of Nicholas N. Paul in Support of Motion for Partial Summary Judgment as to Defendant Mylan (“Paul Mylan Decl.”), and Declaration of Nicholas N. Paul in Support of Motion for Partial Summary Judgment as to Defendant Sandoz (“Paul Sandoz Decl.”).)

**A. The Term AWP, as Used in the Relevant California Statutes and Regulation, Should Be Given Its Plain Meaning as a Matter of Law.**

At all relevant times, the standards by which Medi-Cal reimbursed pharmaceutical providers were set out by regulation and statute, and the meaning of those standards is a question of law. *Blue Cross & Blue Shield v. AstraZeneca Pharms. LP*, 582 F.3d 156, 168 (1st Cir. 2009) (hereinafter, “BCBS”). Consistent with this Court’s prior rulings in related cases, it is clear that the California Legislature and Department of Health Care Services (“DHCS”) (which administers the Medi-Cal program) used the term “average wholesale price” in accordance with its plain meaning. First, that is the preferred reading of any statutory or regulatory term, in that “. . . the words of the statute provide the most reliable indication of legislative intent.” *Rothschild v. Tyco Internat. (US)*, Inc., 83 Cal. App. 4th 488, 496 (2000). See also *Massachusetts*, 608 F. Supp. 2d at 141; *Kraus v. Trinity Management Servs., Inc.*, 23 Cal. 4th 116, 129 (2000). Second, as this Court has found, Defendants “cannot elude the plain language canon of statutory construction” by characterizing the term “average wholesale price” as a term of art, as AWP did not have an “established and settled meaning” in the drug manufacturing

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<sup>8</sup> There are no claims paid at a MAIC at issue in this case.

industry and therefore was not a “term of art.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d. 277, 285 (D. Mass. 2006), *aff’d*, 582 F.3d 156 (1st Cir. 2009). Third, the context in which the term AWP appears – i.e., as a means to determine the Department’s best estimate of the price generally and currently paid by providers for a drug product – supports giving the term its plain meaning as an average of the prices that wholesalers charge providers. Fourth and finally, a plain meaning reading of the term AWP is supported by relevant California regulatory and statutory history.

**B. The Relevant California Regulatory and Statutory History Makes Clear That AWP Was Intended to Be an Estimate of Providers’ Actual Acquisition Prices, Not a Mere “Sticker Price” Unrelated to Real World Prices**

California regulatory and statutory history confirms that, at all relevant times, the term AWP was intended to represent the best estimate of providers’ actual acquisition costs. There is no support in that history for the notion that California regulators or lawmakers ever endorsed or even acquiesced in a system whereby Defendants could report AWPs that were up to ten times the actual average prices at which providers purchased their products. Rather, the record reflects that legislators and DHCS officials were attempting, if slowly or unevenly, to correct for inflated reimbursement based on their imperfect awareness that some manufacturers were distorting the prices they reported to FDB.

Throughout most of the period at issue in this matter, Medi-Cal estimated providers’ acquisition costs at AWP-5% (or “direct price” for specific manufacturers, unrelated to any Defendant herein), pursuant to an amendment to the applicable regulation adopted in 1989. CAL. CODE REGS. tit. 22, § 51513 (West 2006) (Ex. A). The regulatory history demonstrates that California used AWP as a proxy for real world prices paid by providers, albeit with the recognition that the number needed a slight discount. Further, DHCS expressly disavowed any

intent to cross-subsidize allegedly inadequate dispensing fees. As DHCS noted in a 1989 Addendum to its Final Statement of Reasons (“FSR”):

Discounting the dispensing fee may have been agreed to historically; however, current federal regulations at 42 C.F.R. section 447.332, require the Department to make drug reimbursements based on the estimated acquisition cost of the drug without including any loss on dispensing fee requirements.

\* \* \* \*

An analysis of existing elements of Medi-Cal reimbursement, such as the [FUL], MAIC, and direct price, determined that when combined with AWP-5%, they resulted in an overall discount which was equal to the Department’s best estimate of the price generally and currently paid by providers.

Addendum to FSR, R-72-89, at 1, 2-3 (Ex. B). There is no factual support for the theory that DHCS or any California officials sanctioned, or acquiesced in, the reporting of grossly inflated AWPs that were in no way a reasonable proxy for the estimated acquisition costs of the Subject Drugs.

The Legislature made minor adjustments to reimbursement rates during the 1990s, and in 1999 directed Medi-Cal to perform a comprehensive analysis of reimbursement rates. CAL. BUS. & PROF. CODE § 4426 (West 1999) (Ex. C). DHCS contracted with Myers & Stauffer for the study.

By mid 2002, the Legislature was aware that it was not appropriate to continue using AWP-5% as a basis for reimbursement. Apparently as a stop-gap measure, and before being able to fully consider the recently-completed Myers & Stauffer report, the Legislature reduced the reimbursement rate to AWP-10%, and eliminated direct price reimbursement. CAL. WELF. & INST. CODE § 14105.46 (eff. September 30, 2002 – August 15, 2004) (West 2008) (Ex. D). Again, nothing in the record reflects any intent by California to sanction the reporting of AWPs that greatly exceeded reasonable estimates of providers’ actual acquisition costs.

Effective September 1, 2004, the Legislature adopted a comprehensive revision to the pharmacy reimbursement rates being paid by Medi-Cal, reducing the AWP component of the reimbursement formula to AWP-17% and raising dispensing fees to \$7.25 (\$8.00 for nursing home residents), consistent with the findings of the Myers & Stauffer report. CAL. WELF. & INST. CODE § 14105.45 (eff. August 16, 2004 – August 23, 2007) (West 2009) (Ex. E). Nothing in the record supports the notion that, even as late as this, California officials approved the reporting of AWPs that substantially exceeded providers' actual acquisition costs.

In short, the applicable statutory and regulatory history makes it clear that California officials consistently used the term AWP in an effort to estimate the “prices generally and currently paid by providers” for pharmaceutical products. The history shows that California officials have been attempting to play “catch up” with a barrage of inflated AWPs that interfered with the State’s efforts to accurately estimate acquisition costs. As with the Federal government, the legislative history and statutory context demonstrates “slow adaptation to shadowy industry practices, not ratification of them.” *BCBS*, 582 F.3d at 171.

### **III. ARGUMENT**

#### **A. Summary Judgment Standards**

“Summary judgment is appropriate when ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.’” *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting FED. R. CIV. P. 56(c)). “To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party’s position.” *Rogers v.*

*Fair*, 902 F.2d 140, 143 (1st Cir. 1990); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986).

There is no material factual dispute as to any of the elements of Plaintiffs' Count I and Count II Claims for Relief under the CA FCA. The record shows that Defendants caused materially false claims to be submitted to Medi-Cal, and did so knowingly. Moreover, Defendants' government knowledge defense is inadequate as a matter of law.

#### **B. The Elements of Plaintiffs' Claim Under the California False Claims Act**

Plaintiffs' claims in Counts I and II arise under the CA FCA, and the pertinent statute and relevant case law provide the rules of decision that govern the merits of this case. The CA FCA imposes liability for treble damages as well as civil penalties upon any person who does either of the following (among other proscribed acts):

- (1) [As to Count I] knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.
- (2) [As to Count II] knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision.

CAL. GOV'T CODE § 12651(a)(1), (a)(2).

To make out a claim under the CA FCA, the government must establish that (1) a claim was submitted, (2) for payment with government funds, (3) the claim was materially false, and (4) the defendant acted "knowingly." *See generally, Fassberg Constr. Co. v. Housing Auth. of Los Angeles*, 152 Cal. App. 4th 720, 735-36 (2007); *City of Pomona v. Superior Court*, 89 Cal. App. 4th 793, 801 (2001). "Proof of specific intent to defraud is not required." CAL. GOV'T CODE § 12650(b)(2). Notably, the California Legislature expressly mandated that the CA FCA "shall be liberally construed and applied to promote the public interest." *Id.* at § 12655(c); *Pomona*, 89 Cal. App. 4th at 802.

**1. Defendants Caused the Submission to Medi-Cal of False Claims for the Subject Drugs, which Were Paid Using Government Funds.**

There is no material dispute of fact as to the evidentiary support for the first two elements of Plaintiffs' case. Between 1994 and 2004, Medi-Cal providers routinely submitted claims for reimbursement to Medi-Cal (through its fiscal intermediary, Electronic Data Systems (EDS)), for transactions in which the Dey, Mylan and Sandoz Subject Drugs were dispensed to Medi-Cal beneficiaries. The reimbursement at issue includes 950,148 claims involving Dey Subject Drugs, 14,930,147 claims involving Mylan Subject Drugs, and 12,814,958 claims involving Sandoz Subject Drugs. (Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Defendants Dey, L.P. and Dey, Inc. ("CA Dey SOF"), ¶ 1; Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. ("CA Mylan SOF"), ¶ 1; Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Defendant Sandoz Inc. ("CA Sandoz SOF"), ¶ 1; Paul Dey Decl., Ex. 23, Paul Mylan Decl., Ex. 14; Paul Sandoz Decl., Ex. 10, Leitzinger Decl., Ex. A, Leitzinger Report, at ¶ 10.)<sup>9</sup>

Pursuant to the statutory and regulatory reimbursement standards, the claims at issue were adjudicated and paid by Medi-Cal (through EDS, using government funds) at the lowest of either (a) the provider's usual and customary charge, or (b) the lesser of the AWP (as reported by FDB, minus either 5, 10 or 17%) or the Federal Upper Limit (FUL), plus a dispensing fee. By statute, each calculated claim payment was then reduced by an amount varying over time from 10¢ to 50¢ per claim. (CA Dey, CA Mylan and CA Sandoz SOF, ¶¶ 2-5.)

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<sup>9</sup> The CA Dey, CA Mylan and CA Sandoz SOFs were filed contemporaneously with the filing of the instant Memorandum, as were the Declarations of Nicholas N. Paul in Support of Motion for Partial Summary Judgment, which convey all evidentiary exhibits cited within the CA Dey, CA Mylan and CA Sandoz SOFs (some exhibits of which were designated "Confidential" or "Highly Confidential" and were accordingly filed under seal).

With regard to “causing a false claim to have been presented for payment,” this Court has previously held that the alleged conduct of reporting prices not reflective of actual transaction prices is sufficiently causally related to the providers’ submission of claims that would be paid at those prices, as to satisfy the “cause to be submitted” element:

Defendants assert that the claims submitted to the government by providers do not contain any false pricing information because the allegedly inflated AWPs or DPs for Defendants’ drugs are not included on the claim form submitted to Medi-Cal. Although it is true that the claim form that the providers submit to the state does not require the provider to insert a price for the drug, this fact does not require dismissal of a claim under [Cal. Gov’t Code] § 12651(a). Plaintiff’s theory is that the drug manufacturers report false prices for a particular drug to Medi-Cal via the publishing compendium knowing full well that the provider will be reimbursed based on that inflated price when he submits his claim to Medi-Cal for a particular drug .... Thus, although the claim itself may not contain a fraudulent price, it is predicated on an underlying fraudulent pricing scheme. As such, under California law, the allegation that the claim is underpinned by fraud is sufficient.

*California*, 478 F. Supp. 2d at 173. As this Court further held in *Massachusetts*: “Thus, although the manufacturers do not themselves submit claims to the Commonwealth, and the claims do not themselves contain WACs or AWPs, the claims here were ‘predicated on an underlying fraudulent pricing scheme.’ The defendants are thus chargeable with causing false claims to be presented to the Commonwealth.” *Massachusetts*, 608 F. Supp. 2d at 145. Under the CA FCA, to be actionable, the claim need only “be grounded in fraud,” though the claim itself need not be false. *Pomona*, 89 Cal. App. 4th at 802. *See also United States v. Rivera*, 55 F.3d 703, 705-07 (1st Cir. 1995) (fraudulently inflated invoices and requests for loan disbursements from a federally insured lender, which caused HUD and the Department of Health and Human Services to issue certificates of insurance for the inflated loan, caused false claims when the private lender made claims on the insurance after the borrower’s bankruptcy).

**2. Defendants' Reported AWPs Were Materially False Because They Grossly Exceeded The Average Prices Paid By Wholesalers' Customers For The Subject Drugs By Substantial Percentages.**

Plaintiffs' expert, Dr. Leitzinger, used data provided by Dey, Mylan and Sandoz to estimate the average prices paid by pharmaceutical wholesalers' customers [i.e., Medi-Cal providers] for each of the 394 Subject Drug NDCs. (CA Dey SOF, ¶ 27; CA Mylan SOF, ¶25; CA Sandoz SOF, ¶ 22.) Specifically, Dr. Leitzinger calculated the prices that wholesalers paid to Dey, Mylan and Sandoz for each NDC, applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each NDC. His methodology is explained more fully at paragraphs 12 through 20 of his Report, attached as Exhibit A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the "Industry Profile and Healthcare Factbook," published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7% and 5.4%. (CA Dey SOF, ¶ 23; CA Mylan SOF, ¶ 25; CA Sandoz SOF, ¶ 22; Paul Dey Decl., Ex. 23; Paul Mylan Decl., Ex. 14; Paul Sandoz Decl., Ex. 10, Leitzinger Decl., Ex. A, Leitzinger Report, at ¶ 20, n.20.)

Exhibit 4 to Dr. Leitzinger's Report shows, in column (6), the "spread" (i.e., the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the relevant Dey, Mylan and Sandoz NDCs on a quarterly basis from the first quarter of 1994 through the fourth quarter of 2004. (CA Dey SOF, ¶ 24; CA Mylan SOF, ¶ 26; CA Sandoz SOF, ¶ 23; Paul Dey Decl., Ex. 23; Paul Mylan Decl., Ex. 14; Paul Sandoz Decl., Ex. 10, Leitzinger Decl. at ¶ 5.)

*Regarding Dey's 28 NDCs*, for over 94% of the NDC/quarter combinations for which Dr. Leitzinger had complete data, the AWPs reported by Dey exceeded the average net quarterly prices paid by wholesalers' customers by at least 100%. For 62% of those NDC/quarter

combinations, the spread exceeded 300%, with some greater than 800%. (CA Dey SOF, ¶ 25.)<sup>10</sup> Demonstrative charts, based on Dr. Leitzinger's calculations, graphically portraying the extent of the spreads for four Dey Subject Drug NDCs, are attached as Exhibit F. These charts show the gulf between Dey's reported AWPs versus Dr. Leitzinger's calculated "but-for" average net quarterly prices.

***Regarding Mylan's 217 NDCs***, for over 93% of the Mylan NDC/quarter combinations for which he had complete data, the AWP reported by Mylan exceeded the average net quarterly prices paid by wholesalers' customers by at least 100%. For 80% of those NDC/quarter combinations, the spread exceeded 300%, with some greater than 2000%. (CA Mylan SOF, ¶ 27.) Demonstrative charts, based on Dr. Leitzinger's calculations, graphically portraying the extent of the spreads for four Mylan Subject Drug NDCs, are attached as Exhibit G. As with the Dey charts, these charts show the disparities between Mylan's reported AWPs versus Dr. Leitzinger's calculated "but-for" average net quarterly prices.

***Regarding Sandoz's 149 NDCs***, for over 95% of the Sandoz NDC/quarter combinations for which he had complete data, the AWP reported by Sandoz exceeded the average net quarterly prices paid by wholesalers' customers by at least 100%. For 82% of those NDC/quarter combinations, the spread exceeded 300%, with some greater than 2000%. (CA Sandoz SOF, ¶ 24). Demonstrative charts, based on Dr. Leitzinger's calculations, graphically portraying the extent of the spreads for four Sandoz Subject Drug NDCs, are attached as Exhibit H. As with the

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<sup>10</sup> For purposes of calculating the overpayments made by the State for the relevant Dey, Mylan and Sandoz NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Dey by at least 25%. For each remaining claim, he calculated the difference between the actual ingredient cost reimbursed by the State and an amount 25% above the average net price paid by wholesalers to Dey. That difference was the overpayment he found. (Dey SOF, ¶ 26, Mylan SOF, ¶ 28, Sandoz SOF, ¶ 25; Paul Dey Decl., Ex. 23; Paul Mylan Decl., Ex. 14; Paul Sandoz Decl., Ex. 10 (Leitzinger Decl. at ¶ 7).)

Dey and Mylan charts, these four charts also show the significant gap between Sandoz's reported AWPs versus Dr. Leitzinger's calculated "but-for" average net quarterly prices.

As Dr. Leitzinger found, the spreads for Defendants' products were very large. With respect to each Defendant, the spreads consistently exceeded 100% for well over 90% of the relevant NDCs. For Dey, some spreads exceeded 800%; for Mylan and Sandoz, some exceeded 2000%. In the face of this evidence, Defendants cannot reasonably claim that their reported AWPs bear any coherent relationship to the actual average wholesale prices paid by providers for their products.

Defendants have protested that, given the relatively low dollar price of generic drugs, focusing on percentage spreads is unfair. But in dollar terms, the numbers are equally significant. For example, in examining the data for particular quarters, Dey's Albuterol 5MG/ML solution had a reported AWP of \$14.99, while its but-for price was \$1.25; Acetylcysteine 10% vial had a reported AWP of \$59.88 against a but-for price of \$7.47; and Ipatropium Bromide 0.02% solution had a reported AWP of \$44.10 against a but-for price of \$2.35. (Paul Dey Decl., Ex. 23, Leitzinger Decl., Ex. 4 to Ex. A at lines 18, 53, 454.)

As for Mylan, again examining the pricing extant in the NDC/quarters set forth in Dr. Leitzinger's report, Methotrexate 2.5 mg tablet had a reported AWP of \$356.40 compared to a but-for price of \$16.43; Diltiazem 30 mg tablet had a reported AWP of \$ 199.75 against a but-for price of \$14.98; and Clorazepate 3.75 mg tablet had a reported AWP of \$103.74 compared to a but-for price of \$2.51. (Paul Mylan Decl., Ex. 14, Leitzinger Decl., Ex. 4 to Ex. A at lines 41, 105, 149.)

The same holds true for Sandoz. Perphenazine 2 mg tablet in 2004 had a reported AWP of \$68.82 compared to a but-for price of \$3.24; Bupropion HCL 100 mg tablets in 2004 had a

reported AWP of \$96.06 against a but-for price of \$12.73; and in 2002 Atenolol 25 mg tablet's AWP was reported at \$70.25 against a but-for price of \$1.66. (Paul Sandoz Decl., Ex. 10, Leitzinger Decl., Ex. 4 to Ex. A at lines 306, 543, and 623.)

Defendants' experts have asserted that these percentage spreads appear large only because the Subject Drugs are low cost generics; however, this is not necessarily so. For instance, a substantial number of Sandoz NDCs had AWPs well over \$100, which means there were at least \$50 spreads on the corresponding NDCs. So in truth, whether viewed from a percentage basis as this Court has consistently done, or viewed on a dollar basis as insisted upon by the Defendants, there is no genuine issue of material fact but that the AWPs that Defendants reported were false.

There is also no genuine issue of material fact that the reported AWPs were material to the payments made by the State. As this Court found with regard to the Massachusetts program:

[D]efendants cannot prevail on their argument that the false statements were not material. Reporting false WACs had a natural tendency to influence the Commonwealth's actions, by inflating the amounts used to compute EAC, and thus potentially the amount of the Commonwealth's payment. There is no genuine issue as to the materiality of the defendants' false statements when they reported WACs.

*Massachusetts*, 608 F. Supp. 2d at 153.

Here, all of the Subject Drugs were reimbursed based on AWP, FUL or Usual and Customary ("U&C") under California's "lowest of" reimbursement formula. As the State's statutorily defined "lesser of" formula provides (see CAL. WELF. & INST. CODE § 14105.45), AWP is an integral component of the adjudication formula for every single claim reimbursed. When the Defendants published false AWPs, they ensured that any claims for reimbursement for their drugs would be false, including all instances in which the but-for "real" AWPs calculated by Dr. Leitzinger were less than the FUL or U&C on which such claims were paid. In other words, had Defendants reported AWPs that reasonably reflected providers' acquisition costs,

those AWPs would have controlled the payment level in all instances in which they were less than the FUL or U&C. Defendants' false AWPs were therefore material to all instances in which California reimbursed a claim based on the reported AWPs; and were also material to all claims paid by Medi-Cal when the underlying NDC's actual but-for price, if it had been truthfully reported as the AWP, was lower than the FUL or U&C on which the claim was paid.

### **3. Defendants Acted Knowingly**

Finally, Plaintiffs must prove that the Defendants knew that the claims were false or fraudulent. The CA FCA, like the federal Act, defines "knowingly" to include acting (A) with actual knowledge of the information, (B) in deliberate ignorance of the truth or falsity of the information, or (C) with reckless disregard of the truth or falsity of the information. As with the federal FCA, "[p]roof of specific intent to defraud is not required." CAL. GOV'T CODE § 12650(b)(2). Knowing conduct under the FCA may be established on summary judgment. *See, e.g., United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 471 (5th Cir. 2009) (granting summary judgment to government on scienter in FCA case); *United States v. President and Fellows of Harvard College*, 323 F. Supp. 2d. 151, 190 (D. Mass. 2004) (granting summary judgment to government on defendant's knowledge under the FCA). Here, there is no genuine dispute of fact: Defendants acted knowingly in causing the submission of false claims.

Two aspects of the CA FCA are critical in this regard. First, as noted above, "[p]roof of specific intent to defraud is not required." CAL. GOV'T CODE § 12650(b)(2). California is not required to prove that Defendants intended to defraud Medi-Cal by reporting false AWPs. "The [CA FCA] contains the same scienter requirements as the federal law. The [CA FCA] does not demand a deliberate lie but allows for liability where the defendant acts in deliberate ignorance or in reckless disregard of the truth of the claim." *Thompson Pacific Construction, Inc. v. City of Sunnyvale*, 155 Cal. App. 4th 525, 549-50 (2007). Second, the statute expressly focuses on

Defendants' knowledge or reckless disregard "of the information." CAL. GOV'T CODE § 12650(b)(2)(A)-(C) (emphasis added). California is not required to prove that Defendants knew or recklessly disregarded the meaning of the applicable statutory or regulatory standards. Rather, to establish scienter, Plaintiffs need show no more than that Defendants acted with knowing or reckless disregard of the falsity of the information they reported. Specifically, in addition to showing the undisputed facts which demonstrate the existence of actionable AWP spreads on the Subject Drugs, Plaintiffs need only show that Defendants were aware of how Medi-Cal reimbursed providers for Defendants' drugs in reliance on prices reported by Defendants to FDB; that Defendants reported their AWPs to FDB; and that Defendants knew their AWPs were not reflective of actual average wholesale prices.

Dr. Leitzinger's spread calculations were based on the difference between the reported AWPs for Defendants' products and information from Defendants' business records that reflected the actual prices at which those products were being acquired by providers. (CA Dey SOF, ¶ 27; CA Mylan SOF, ¶ 25; CA Sandoz SOF, ¶ 22.) At all relevant times, Defendants knew the prices at which they sold their products to wholesalers as well as to large chains and group purchasing organizations with which they had contracts. *Id.* Notwithstanding their knowledge of the real prices that providers were paying, which they closely monitored, each Defendant virtually always reported AWPs creating spreads in excess of 100%, most often in excess of 300%. (CA Dey SOF, ¶ 25; CA Mylan SOF, ¶ 27; CA Sandoz SOF, ¶ 24.) The following facts comprehensively illuminate each Defendant's knowing conduct.

**a) Dey**

Throughout the relevant time period, Dey admits that it set the AWPs for its products – and in particular set the AWPs for its generic drugs – before they were first sold. Dey generally

did not subsequently change its AWPs once initially set. When Dey was the first manufacturer to market a generic product, rather than setting and reporting AWPs that reflected prices generally and currently paid by providers for its drugs, Dey reported AWPs for such generics at approximately 10% off the brand AWP, and generally left that price unchanged. (CA Dey SOF, ¶¶ 6-8, 30.) Alternatively, when Dey launched a product for which there were other generic competitors, it set the AWP by reference to the competitor's AWP. In the face of competition in the generic marketplace, Dey would lower the actual selling price of its drugs. (CA Dey SOF, ¶¶ 9-10.) However, Dey generally failed to change its reported AWPs regardless of declining selling prices, notwithstanding that it knew that the combination of lowered sales prices and an unchanged AWP served to increase the reimbursement spread on such products. (CA Dey SOF, ¶¶ 11-12.) FDB published Dey's AWPs from 1992 to 2003, during which the only AWPs listed in FDB for Dey drugs were those reported by Dey. (CA Dey SOF, ¶ 15.) Dey was aware that it was necessary to report AWPs to FDB in order for its products to be reimbursed by third-party payors, such as Medi-Cal. Dey further admits that it did not lower its AWPs because, given the existence of numerous reimbursement systems that relied on AWP, its customers would not buy Dey products if it lowered the AWPs on those products. (CA Dey SOF, ¶¶ 13-14.) Because Dey directly negotiated prices for its products with contract customers, it knew the price that these customers actually paid for its products, even when they were shipped through a wholesaler. (CA Dey SOF, ¶ 28.)

Dey furthermore maintained a computer database intended specifically for Medicaid Average Manufacturer Price ("AMP") calculations, which contained the actual average prices for all of Dey's drug products. Dey calculated its average sales prices for its products at least every month, along with analyses of monthly net sales, average prices per carton and unit, and monthly

net sales after rebates, discounts and administrative fees. Dey also generated monthly product summary reports showing wholesale cost, contract cost, and chargeback differences per drug product. (CA Dey SOF, ¶¶ 16-18.) Nevertheless, despite this wealth of internal actual pricing data, Dey sent FDB only its (brand or competitor-derived) AWPs; not its actual contract pricing or AWPs reflective of prices generally and currently paid for its products. (CA Dey SOF, ¶¶ 11, 18.)

Finally, Dey was not only specifically aware of Medi-Cal's reimbursement policies, but was particularly aware of the reimbursement rates for Dey's products provided under Medi-Cal's AWP-based reimbursement system. (CA Dey SOF, ¶¶ 20, 22.)

**b) Mylan**

Throughout the relevant time period, Mylan set AWPs for its products and reported those prices to pricing compendia, including FDB. Mylan set the AWPs for its products without attempting to have those numbers reflect market prices. (CA Mylan SOF, ¶¶ 6-7.) When it was the first company to market a particular generic product, Mylan generally set and reported as AWPs for its products prices that were 10% below the AWP for the corresponding brand product. However, when Mylan launched a product and there was already a competitive generic product on the market, Mylan set its AWP by reference to the competitor's AWP. (CA Mylan SOF, ¶¶ 8-9.)

Mylan knew that the generic market was very competitive, and that market prices for generic drugs tended to decline significantly after additional participants entered the market. Nonetheless, Mylan admits it generally did not change its reported AWPs in response to changes in transaction prices for the Mylan Subject Drugs, and further admits that it did not sell its products at AWP. (CA Mylan SOF, ¶¶ 10-12.) Mylan contracted with large pharmacy chains

for the sales of its products, and was aware of the actual prices at which its drugs were sold, maintaining databases to track those prices. It also calculated accurate estimates of sales prices for its products on a regular basis. (CA Mylan SOF, ¶¶ 15-17.) However, Mylan did not report its transactional prices, or any averages or compilation of those prices, to FDB or to Medi-Cal as its AWPs. (CA Mylan SOF, ¶¶ 18-19.) Mylan knew that its reported AWPs did not reasonably reflect providers' actual acquisition costs. (CA Mylan SOF, ¶ 26.)

Mylan knew it had to report AWPs to FDB in order for Medi-Cal to reimburse providers dispensing Mylan products, and Mylan knew that FDB published the AWPs reported to it by Mylan as the AWPs for Mylan's drugs. (CA Mylan SOF, ¶¶ 13-14.) Mylan was aware of Medi-Cal reimbursement policies, and Mylan was aware that Medi-Cal reimbursed providers for pharmaceutical products based, in part, on the reported AWPs of the products. (CA Mylan SOF, ¶¶ 20-21.)

**c) Sandoz**

Throughout the relevant time period, Sandoz set AWPs for its products and reported those prices to pricing compendia, including FDB. At the time Sandoz launched a new product, there was no predictable relationship between the AWP Sandoz set for that product and the price at which Sandoz actually sold that product. When it was the first company to market and sell a particular generic product, Sandoz generally set and reported as an AWP for that particular product a price 10 to 20% below the AWP for the corresponding brand product, regardless of the price at which Sandoz actually sold that product. When Sandoz launched a product and a competitive generic product was already on the market, Sandoz set its AWP by reference to the competitor's AWP. (CA Sandoz SOF, ¶¶ 6-10.)

Sandoz knew that the generic market was very competitive, and that market prices for generic drugs invariably declined significantly after additional participants entered the market. Yet Sandoz generally did not change its reported AWPs in response to changes in transaction prices for its products, instead making it a practice to set a product's AWP at launch, and thereafter not change that AWP. When Sandoz did change its AWPs, the change was usually in the form of an increase in AWP, even though Sandoz did not sell its products at AWP. Sandoz did not define AWP as a price paid by retailers to wholesalers for its products. Instead, AWP was a price set by Sandoz only to ensure a generic designation from the pricing entities, such as FDB. (CA Sandoz SOF, ¶¶ 10-12, 26.)

Sandoz maintained databases through which it regularly tracked the prices at which its products were being sold, and for internal business purposes Sandoz would calculate the average sales prices for its products on a regular basis. (CA Sandoz SOF, ¶¶ 15-16.) Sandoz contracted directly with large retail pharmacy chains and group purchasing organizations for the sale of its products, but Sandoz did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products' AWPs. Furthermore, there was no fixed or predictable relationship between the AWPs that Sandoz reported to FDB and the prices at which its products were sold to the retail class of trade. (CA Sandoz SOF, ¶¶ 17-19.)

Sandoz knew it was necessary to report AWPs to FDB in order for its products to be reimbursed by third party payers, such as Medi-Cal, and FDB published the suggested AWPs reported by Sandoz as the AWPs for Sandoz's products. Sandoz was aware of Medicaid and Medi-Cal reimbursement policies in general, and Sandoz was aware that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWPs of the products. (CA Sandoz SOF, ¶¶ 13-14, 20-21.)

**d) Plaintiffs have established that Defendants acted knowingly.**

None of the Defendants can aver to any federal or California statute, regulation or policy that dictated or endorsed their practice of reporting grossly inflated AWPs, prices untethered to any measure of actual average acquisition costs. The relevant statutes and regulations were premised on the EAC concept, which assumed and required that Defendants would report prices reflective of those generally and currently paid by providers for their drugs. Instead, Defendants set, reported and maintained AWPs that were 10% below the brand AWP, or based on their competitors' AWPs, knowing that those prices were not in any way an average of the wholesale prices for their products. These facts constitute knowing conduct by Defendants with regard to their obligation to truthfully report prices consistent with California's EAC-based Medicaid reimbursement system.

Plaintiffs are aware that this Court declined to grant summary judgment to Massachusetts, finding that there was a factual issue as to scienter given that defendants therein “produced sworn testimony that they believed WACs to be merely an invoice price and that they used it as such, as well as some evidence that some others understood WAC in the same way.” *Massachusetts*, 608 F. Supp. 2d at 155. However, because of the significant differences between WACs and AWPs, as well as the Defendants’ admissions in this matter, this Court’s holding in the Massachusetts case should not be controlling here.

Unlike WACs, which could plausibly be understood as representing invoice prices, the purpose of reporting AWPs was to provide a reference price known to be determinative of reimbursement amounts paid by third-party payors, including government payors highly dependent on the accuracy of such information – such as, for instance, Medi-Cal. Defendants cannot point to a reasonable alternative use or meaning for the term AWP. Their contentions

notwithstanding, Defendants were required to know and follow the law when they elected to participate in Medi-Cal. The applicable statutes and regulations use the term AWP in its plain meaning as a means to derive an estimate of providers' acquisition costs for Defendants' products. Defendants admit that they ignored any reasonable interpretation of the terms "average wholesale price," "estimated acquisition cost," or "prices generally and currently paid by providers" – and instead knowingly set, maintained and reported artificially inflated AWPs. In so doing, they breached the bedrock principle underlying the False Claims Act, *viz.*, that "[m]en must turn square corners when they deal with the government." *Rock Island, A.&L. R. Co. v. United States*, 254 U.S. 141, 143 (1920).<sup>11</sup>

#### **IV. DEFENDANTS' GOVERNMENT KNOWLEDGE DEFENSE IS INADEQUATE AS A MATTER OF LAW**

##### **A. The Context of California's Claims Renders the Government Knowledge Defense Inapplicable.**

The factual context of this case makes any government knowledge defense inapplicable as a matter of law. This case does not involve the administration of a discrete government contract, but rather the knowing manipulation of Medi-Cal's pharmacy reimbursement system. The relevant standards were at all times openly promulgated by statute and regulation, which Defendants were required to know and follow. Moreover, Defendants never sought, or obtained, government approval to report grossly inflated AWPs set at levels wholly disconnected from actual average wholesale prices.

Defendants chose to manipulate their AWPs precisely because they knew that California's Medicaid program had implemented the federally-mandated EAC requirement by

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<sup>11</sup> As the Court has more recently stated: "This observation has its greatest force when a private party seeks to spend the Government's money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law." *Heckler*, 467 U.S. at 63.

adopting AWP as one of the core reference prices by which Medi-Cal would estimate acquisition costs. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 95 (D. Mass. 2007) (recognizing manipulation by manufacturers of existing system: “The different pharmaceutical companies unfairly took advantage of the system by setting sky high prices with no relation to the marketplace”). Even if Defendants had fully apprised Medi-Cal officials of the grossly inflated nature of their reported prices by providing consistent and detailed information about the prices generally and currently paid for their drugs, which they did not do, Medi-Cal was still required to reimburse providers pursuant to the governing standards. Here, as in *United States v. Estate of Rogers*, 2001 WL 818160 (E.D. Tenn. 2001), “[i]t is the defendant’s compliance or lack of compliance with the nondiscretionary regulations … that determines whether the defendant’s conduct results in the submission of false claims under the FCA.” *See United States ex rel. Oliver v. Parsons & Co.*, 195 F.3d 457, 463 (9th Cir. 1999) (the meaning of non-discretionary regulations is a matter for judicial interpretation, and the falsity of a claim is determined by whether the claim was “accurate in light of applicable law”). California law has long been in accord. *See Brown v. Board of Med. Qual. Assur.*, 86 Cal. App. 3d 548, 555 (1978) (“Dr. Brown’s contention that he billed in conformity with community practice is to no avail. The practice in the profession does not establish the standard exacted by law.”)

It is hornbook law that the government’s failure to enforce a law does not excuse non-compliance. Here, given the clear language of the governing regulations, Defendants cannot be heard to cry foul on the basis that the Government should have ferreted out their scheme earlier and not have allowed it to continue. As the First Circuit has explained, “it is not true that once a government agency smells a rat, the agency must exterminate it forthwith or allow it the run of the public’s house in perpetuo.” *U. S. v. Michael Schiavone & Sons, Inc.*, 430 F.2d 231, 233 (1st

Cir. 1970). Defendants knew that the State was using their reported AWPs to reimburse providers, and that it did so pursuant to federal and State regulations that limited reimbursement to the State's best estimate of providers' acquisition costs. (CA Dey SOF, ¶ 14; CA Mylan SOF, ¶ 13; CA Sandoz SOF, ¶¶ 13, 21.) Plaintiffs need prove no more.

**B. The Record Does Not Raise a Genuine Issue of Material Fact That Would Support a Government Knowledge Defense.**

To prevail on any government knowledge-based argument or defense, Defendants must show that the "government [possessed] knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false." *Massachusetts*, 608 F. Supp. 2d at 148. Defendant would also have to show undisputed evidence that not only did it disclose the conduct at issue, but that the government formally, publicly and affirmatively approved of the alleged wrongful price reporting conduct. *See, e.g., United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) ("agency interpretations are only relevant if they are reflected in public documents .... The non public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant.").

In *People v. Duz-Mor Diagnostic Lab., Inc.*, 68 Cal. App. 4th 654 (1998), representatives of Duz-Mor Lab discussed certain billing problems with a Medi-Cal representative, who advised the lab to "unbundle" its billing for certain tests. The Court of Appeal held that there was no violation of the CA FCA given that "Duz-Mor adopted the billing practice at issue here on the instructions of a Medi-Cal representative, and did not knowingly make a false claim." *Id.* at 672. Similarly, in *Laraway v. Sutro & Co.*, 96 Cal. App. 4th 266 (2002), a Sutro representative traveled to New York on behalf of the Pasadena School District without getting pre-approval for his travel expenses, as required by school board policies. District officials nonetheless directed Sutro to bill for its expenses after the trip. The Court of Appeal held that "there can be no false

claim where a contractor has submitted a claim in accordance with government directions, even if the procedure was improper.” *Id.* at 277 n.4. And in *American Contract Services* [“ACS”] v. *Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854 (2002), the Department of General Services cancelled a bid solicitation in favor of a “sole source” contract with Allied. Addressing competitor ACS’s allegation that Allied’s invoicing was false because of the sole source contract, the court found no CA FCA violation where the alleged wrongdoing “was known to and initiated by the government.” *Id.* at 865.

These California cases prescribe the level of knowledge and acquiescence necessary for a defendant to prevail on an affirmative defense of government knowledge. Since Defendants cannot demonstrate a similar type of knowledge and approval on the part of Medi-Cal, partial summary judgment in favor of Plaintiffs on Defendants’ government knowledge defense is appropriate.

**1. California Did Not Know the Specifics of Defendants’ Price Reporting Conduct or the Actual Prices Generally and Currently Paid for Their Products.**

Absent from the extensive factual record in this case is any evidence that Defendants fully informed the federal government or California of the relevant facts concerning their reported prices, or that any government official acted “with full knowledge of the relevant facts.” Defendants must make a particularized showing of actual facts. *Massachusetts*, 608 F. Supp. 2d at 148; *See also Shaw v. AAA Eng’g & Drafting, Inc.*, 213 F.3d 519, 534 (10th Cir. 2000) (entertaining government knowledge defense only where government’s knowledge as to the true facts is extensive). Defendants never communicated to Medi-Cal a reasonable estimate of the average wholesale prices that providers paid for the Subject Drugs, nor any measure of the extent of the spreads between the Subject Drugs’ AWPs and the actual prices generally and currently

paid by providers for the same Drugs. (Paul Dey Decl., Ex. 1; Paul Mylan Decl., Ex. 1; Paul Sandoz Decl., Ex. 1, Gorospe Decl. at ¶¶ 11-12.)

Here, only the manufacturers – not Medi-Cal – had ready information about the prices generally and currently paid by providers for the Subject Drugs, and the manifold variations between actual transactional prices for their drugs and the AWPs that Defendants reported to the compendia for publication (as demonstrated in Exhibit 4 to Dr. Leitzinger’s expert report).<sup>12</sup> California does not dispute that there were some federal OIG and state studies concerning drug reimbursement amounts in the Medicaid and Medicare programs during the relevant time period. However, these studies at most provided Medi-Cal with a generalized alert that there were problems with some manufacturers’ reported AWPs. But by no means did these studies provide California with actual knowledge of the drug-by-drug mega-spreads inflicted on Medi-Cal by the Defendants’ grossly inflated AWPs. Given the extreme variations in spreads among different manufacturers, for different drugs, for individual NDCs, and for different time periods, no generalized knowledge of AWP inflation could have constituted the type of affirmative disclosure required for Defendants to legitimately invoke the government knowledge defense, i.e., “knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false.” *Massachusetts*, 608 F. Supp. 2d at 148.

**2. The Government Never Approved of Defendants’ Price Reporting Conduct, and Defendants Cannot Show Government Approval of the AWPs They Reported.**

As this Court has stated, evidence of government knowledge concerning a false claim allegation “does not support an across the board government knowledge defense [where] there is no evidence of government sanction.” *Massachusetts*, 608 F. Supp. 2d at 151; *see also, United*

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<sup>12</sup> Paul Dey Decl., Ex. 23; Paul Mylan Decl., Ex. 14; Paul Sandoz Decl., Ex. 10 (Leitzinger Decl., Ex. A).

*States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999) (falsity negated where the government “knows and approves of the particulars of a claim for payment before that claim is presented ....”); *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327 (9th Cir. 1995) (where the defendant and the government “so completely cooperated and shared all information,” defendants’ claims were not knowingly false).

Defendants cannot show any evidence of communication with any Medi-Cal official in which that official approved of their fraudulent AWP price reporting (following, of course, the requisite full disclosure from Defendants), despite exhaustive discovery of State officials and extensive production of documentary materials.<sup>13</sup> During the relevant time period, no member of DHCS’s Pharmacy Policy Section authorized Defendants (or any other manufacturers) to report AWPs that exceeded good faith estimates of the amounts generally and currently paid by providers for the Subject Drugs. (Paul Dey Decl., Ex. 1; Paul Mylan Decl., Ex. 1; Paul Sandoz Decl., Ex. 1, Gorospe Decl. at ¶ 12.)

Defendants also cannot show that their false price reporting was based on some implicit understanding that the government had approved of the reporting of “sky high prices unmoored from the acquisition costs of providers.” *California*, 478 F. Supp. 2d at 173. It is inconceivable that AWPs which were set and reported with reference to another drug manufacturer’s reported prices could satisfy the requirement to report prices generally and currently paid by providers. Nor could an implied government tolerance for some modest “understood” spread be deemed an endorsement of a price reporting practice that blatantly disregards the meaning of AWP as a statutorily defined measure of EAC. Dr. Leitzinger’s tables in Exhibit 4 to his report, setting out

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<sup>13</sup> If any such evidence of explicit, fully informed and formal government approval existed, of course, defendants should have such evidence in their own possession in any event. None was produced to Plaintiffs in response to discovery demands.

Defendants' reported AWPs in comparison to the average prices being paid by providers, demonstrate huge variations between AWPs and actual transaction costs. No government reports could possibly have alerted Medi-Cal to the magnitude of such pricing inflation, let alone to the specifics regarding the 394 NDCs included in the Subject Drugs.

## V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their Motion for Partial Summary Judgment as to liability under Counts I and II of the First Amended Complaint.

Dated: November 24, 2009

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on November 24, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul  
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